IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MARYLAND

RYAN & JULIET FOSTER	*	
	*	
v.	*	Case No.: CCB-03-2512
	*	
LEGAL SEA FOODS, INC.	*	
and	*	
GREAT EASTERN MUSSEL FARMS, INC.	*	
	*	
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MEMORANDUM

Defendants Legal Sea Foods, Inc. ("Legal") and Great Eastern Mussel Farms, Inc. ("GEMF") have moved for summary judgment as to plaintiffs' claims of negligence (Count I), strict liability in tort (Count II), and breach of warranty (Count III). All three counts are based on the allegation that plaintiffs Ryan and Juliet Foster (the "Fosters" or, when mentioned individually, "Ryan" and "Juliet") contracted the Hepatitis A Virus ("HAV") from eating raw or undercooked mussels harvested by GEMF and prepared and served at Legal.

Defendants move to exclude testimony by plaintiffs' experts, Dr. Joseph S. Galati ("Dr. Galati") and Roy E. Costa ("Costa"), that Legal's mussels were the source of the Fosters' HAV on the grounds that these experts are not qualified to provide such testimony and that their conclusions are not supported by reliable methodologies. Defendants further move for summary judgment, taking the position that if the experts' opinions that GEMF's and Legal's mussels caused the Fosters' HAV are excluded, plaintiffs are left without evidence to establish causation, an essential element of their claims. For the reasons that follow, I will grant defendants' motions to exclude and for summary judgment.

I.

A.

The facts viewed in the light most favorable to the Fosters, the non-moving party, are as follows. The Fosters, married attorneys from Houston, spent the night of February 7, 2002 in Baltimore en route to a hearing in Delaware. (Legal's Ex. 3, Juliet Dep. 3:5-13, Sept. 2, 2004 [hereinafter Juliet Dep. Sept.].) They stayed near Baltimore's Inner Harbor and dined at Legal, where, among other dishes, they ordered steamed mussels as a shared appetizer. (*Id.* at 6:16-7:1, 10:8-16.) They ate "some [of the mussels] and then as [they] got further down into the dish [they] noticed that some of them were not all the way open [and] some of them were altogether closed[,] so [they] stopped eating them."[1] (*Id.* at 12:1-11.) Juliet stated that, prior to discovering those that were unopened, she did not notice anything wrong with the mussels. (*Id.* at 14:3-13.) When their waitress returned, the Fosters told her that some of the mussels were unopened and asked that they be returned to the kitchen and cooked.[2] (*Id.* at 12:5-7.) The waitress took the mussels away and later returned with what appeared to be the same batch, but hotter and opened. (*Id.* at 12:7-11.)

On the same business trip when the Fosters ate at Legal in Baltimore, at least Ryan, and possibly Juliet, also had meals at a Burger King and the Bean Bag Café in Delaware. (Legal's Ex. 2, Ryan Dep. 14:10; 43:7-13, Apr. 5, 2007 [hereinafter Ryan Dep. Apr.].) In addition,

[1] As Roy Costa, one of plaintiffs' experts, explains, when mussels are closed, it indicates that they have not been sufficiently cooked. "Mussels have a ligament that joins the two shells together, when properly cooked this ligament contracts and the shells open. If undercooked the shells remain closed." (GEMF's Ex. 1, Costa Report I, Aug. 19, 2004 at 2 [hereinafter Costa Report I.].)

[2] For the purposes of this motion, defendants concede that the mussels Legal served the Fosters during the dinner in question were uncooked or undercooked and that the Fosters subsequently contracted HAV. (Legal's Mem. Supp. Summ. J. 21.)

receipts indicate that during the month leading up to his hospitalization, Ryan dined out at several other restaurants and eateries. (*Id.* at 42:16-43:3.)

Approximately thirty-three days after the Fosters' dinner at Legal, on March 12, 2002, Ryan developed severe flu-like symptoms and was admitted to the emergency room of St. Luke's Episcopal Hospital in Houston, Texas, "complaining of abdominal pain, fever, chills, and night sweats [that began] several days prior to admission." (Legal's Ex. 24, Galati Report on Ryan 1.) Ryan remained hospitalized until March 18, 2002, during which time he "developed generalized abdominal pain associated with nausea and vomiting. His stools became clay colored and he developed jaundice." (*Id.*) Based on a number of serologic studies, doctors diagnosed Ryan with acute HAV. (*Id.*) When Ryan was first admitted to the hospital, he was under the care of his internist, Dr. Ann Radcliffe, who eventually referred him to Dr. Galati for consultation on his acute HAV and hepatic failure. (*Id.*; Legal's Ex. 18, Galati Curriculum Vitae 10 [hereinafter Galati CV].)

On April 4, 2002, about three weeks after Ryan's hospitalization, Juliet experienced similar severe flu-like symptoms and was hospitalized and diagnosed with second-degree HAV. (Legal's Ex. 14, St. Luke's Episcopal Hospital Patient Information - Juliet, Apr. 4; Legal's Ex. 25, Galati Report on Juliet 1.) Because her case was less severe than Ryan's, she spent just one night in the hospital. (Legal's Ex. 15, St. Luke's Episcopal Hospital – Juliet Discharge Information.)

This litigation followed, initiated by plaintiffs' original complaint against Legal, dated August 29, 2003.

B.

Dr. Joseph Galati and Roy Costa are plaintiffs' experts and the subjects of defendants' motion to exclude. Dr. Galati specializes in treating liver disease, including HAV. (Legal's Ex. 13, Galati Dep. 18:7-8, June 1, 2007.) Since 1999, Dr. Galati has served as the Medical Director of the St. Luke's Texas Liver Institute and has worked in private practice for the Gastroenterology and Hepatology Liver Specialists of Texas since 2001. (Galati CV at 2.)

In probing the source of Ryan's HAV, Dr. Galati took a history, "extensively" questioning Ryan about his behavior, including his sexual habits, travel, drug use, blood transfusions, and eating in the months leading up to his illness. (Legal's Ex. 4, Ryan Dep. 33:3-12; 42:11-12, Sept. 2, 2004 [hereinafter Ryan's Dep. Sept.]; Galati Report on Ryan 2.) Because HAV typically has an incubation period of between twenty and fifty days, Ryan's conduct between two and seven weeks prior to becoming ill is particularly relevant. (Galati Report on Ryan 2.) Neither the Fosters nor Dr. Galati can recall whether Ryan informed Dr. Galati during these interviews about his meals at Burger King and the Bean Bag Café. (Ryan Dep. Apr. 14:10; 43:7-13.) In any event, based on his detailed questioning of Ryan, Dr. Galati concluded that, besides Legal's mussels, "there [were] no other obvious risk factors for acquiring the hepatitis A" and therefore the mussels were more likely than not the source of Ryan's HAV. (Galati Report on Ryan 2.) Dr. Galati's "opinion within a reasonable degree of medical certainty [is] that in Mr. Foster's particular case, it is most probably that consuming the undercooked mussels is the causative factor leading to his acute hepatitis A infection." (*Id.*)

In forming his opinions as to Juliet, Dr. Galati reviewed her hospital records and saw her as a patient in his office on April 17, 2002. (Galati Report on Juliet 1-2.) He subsequently concluded that, although Legal's mussels may be the source of her HAV, another likely source

was her contact with Ryan. (*Id.* at 2.) He stated that "[Juliet's] risk factor for hepatitis A would include both the consumption of partially cooked mussels in Baltimore, and the household transmission from her husband," and that it would be difficult to determine precisely which one was the cause of her illness. (*Id.*)

Plaintiffs' second expert witness, Roy Costa, is a registered sanitarian with a bachelor's degree in fisheries biology from the University of Arizona. (Legal's Ex. 21, Costa Dep. 46:16-19, 47:1-2, Oct. 29, 2004.) Costa is "an expert in the environmental health field that involves water and foods, soils and infection control." (*Id.* at 46:10-12.) He spent twenty-one years as a sanitarian for the state of Florida, inspecting restaurants and facilities for compliance with state sanitation standards and investigating the sources of disease outbreaks. (*Id.* at 22:10-25:6, 28:6-29:15.) Costa estimates that he has conducted over 100 investigations into outbreaks of food-borne illnesses, approximately five percent of which involved HAV, and more than 10,000 inspections of public facilities for compliance with state health and sanitation standards. (*Id.* at 28:6-14, 29:10-30:2.) At present, Costa runs Environ Health Associates, which "provide[s] auditing, inspection, HACCP plan development, marketing research, environmental mitigation[,] [a]nd . . . expert testimony." (*Id.* at 9:21, 15:3-7.) Costa has served as an expert witness in cases involving food contamination, including three cases involving HAV contracted from food (none seafood) and several cases where shellfish was contaminated with diseases other than HAV. (*Id.* at 18:2-22:4.)

Although Costa has never met with the Fosters personally, in preparing his opinion, he has reviewed documents pertaining to this case and to the Fosters' treatment, diagnoses, and behavior prior to their infection, as well as literature on shellfish generally, HAV in mussels, and

food safety. (*Id.* at 41:16-42:1, 42:12-18, 43:8-14; Costa Report I at 3.) Costa also considered Legal's Food Safety Plan and its sanitation in general (*id.* at 4-5) and GEMF's mussel harvesting practices and facilities (GEMF's Ex. 3, Costa Report III, Apr. 13, 2006 at 1 [hereinafter Costa Report III]). Additionally, Costa conducted an epidemiological analysis, which considered "[t]he incubation period for HAV, [which] is from 15 days to about 50 days" (averaging around 30 days) in light of the timing of the onsets of the Fosters' symptoms. (Costa Report I at 4.)

Costa completed three expert reports concerning the source of the Fosters' HAV. The first, dated August 19, 2004 ("Costa Report I"), focused on Legal's food sanitation and cooking procedures and the likelihood that Legal served the Fosters uncooked mussels that contained HAV (GEMF's Ex. 1); the second, dated November 12, 2004 ("Costa Report II"), responded to defendants' experts on the mussels' source and harvesting, as well as shellfish generally as a source of HAV (GEMF's Ex. 2); and the third report, dated April 13, 2006 ("Costa Report III"), considered GEMF's mussel harvesting practices in light of this batch's potential contamination (GEMF's Ex. 3). In his first report, Costa concluded that, "[w]ithin a reasonable degree of scientific certainty, . . . more likely than not, Ryan and Juliet Foster unknowingly consumed raw mussels mistakenly served to them by Legal Seafoods . . . and furthermore the mussels were contaminated with a highly virulent pathogen, HAV." (*Id.* at 5.) In his April 2006 report, Costa augmented his conclusions with the opinion that "[t]he most likely source of hepatitis in the mussels consumed by [the Fosters] within a great degree of scientific certainty, certainly greater than 51%, is the use of polluted Tenants Harbor seawater by [GEMF] to purge its mussels." (Costa Report III at 8.)

C.

The Fosters allege that Legal was negligent in its handling and preparation of contaminated mussels that caused plaintiffs' HAV. (2d Am. Compl. ¶¶ 9, 12, 19.) Legal's food preparation and sanitation methods are a primary subject of expert Roy Costa's first report in which Costa examined Legal's cooking procedures, Hazard Analysis Critical Control Point ("HACCP") plan,[3] and food laboratory. Costa's report explains that "Legal['s] cooking policies require shellfish to be steamed twice[;] after the first heat treatment the cook looks for unopened mussels, the mussels are rearranged in the cooker and then steamed again." (Costa Report I at 2.) In addition, Legal "maintains a food laboratory that tests incoming raw shellfish for quality attributes such as coliform count. Tests are also performed to detect E coli, which is a closer estimate or indicator of fecal pollution. However, there is no testing for virus[es] . . . ." (*Id.* at 4-5.)

Costa concluded that "[t]he fact that the unopened mussels were served to the Fosters is a breakdown in procedures, as the steaming process should result in fully opened and cooked mussels." (*Id.*) As a result, "[m]ore likely than not, HAV survived ineffective steaming in a batch of undercooked mussels that [the Fosters] shared at the restaurant." (*Id.* at 4.) Because "cooking temperature data from the time in question are not provided, it is impossible to tell whether Legal was actually taking the final temperature of cooked mussels." (*Id.*) Costa's report emphasized the importance of Legal's properly cooking shellfish to guard against HAV, stating that "[t]he only safeguard from the hazard of HAV in shellfish is thorough cooking, not

[3] Although Costa states that the Food and Drug Administration ("FDA") requires Legal to have an HACCP plan in place, defendants' expert, Dr. Robert J. Price ("Dr. Price"), counters that "HACCP plans are recommended, but not mandated by the" FDA and that "[m]any restaurants do not have HACCP plans." (Legal's Ex. 20, Robert J. Price Report, Oct. 8, 2004 at 2 [hereinafter Price Report].) As a result, Dr. Price concludes that "the fact that Legal . . . has a HACCP plan demonstrates their commitment to food safety." (*Id.*)

tags, not the absence of coliform bacteria, and certainly not the certification of growing waters."[4] (*Id.*)

Costa suggests that Legal "may be relying too much on their laboratory as a means of ensuring the safety of their finished products . . . [when] only cooking can be relied upon as a critical control point," which "is a serious flaw from a food safety perspective." (*Id.*) Costa found Legal's HACCP plan deficient in several other respects, including its failure "to list shellfish as a product that needs to be controlled through cooking" and its lack of a scheduled verification of the plan, which is necessary to "ensure[] that the plan is effective and is being carried out accordingly." (*Id.*)

D.

On February 2, 2005, plaintiffs filed a second amended complaint adding GEMF, a seafood dealer, as a defendant and alleging that GEMF "provided the contaminated mussels, which caused Plaintiffs' illness, to Legal." (2d Amended Compl. ¶ 33.) According to the Fosters, GEMF sold Legal mussels that contained HAV due to being harvested from or purged with polluted water. (*Id.* at ¶ 34.)

According to Endicott Davison, Jr., GEMF's corporate designee, GEMF, as a shellfish dealer, acquires its mussel stock either by purchasing it from independent mussel harvesters or by growing it on its own raft vessel. (Pls.' Ex. 5, Davison Dep. 37:1-8, Apr. 17, 2007.) The mussels sold to Legal were "purchased from independent mussel fishermen that fish wild mussels along the coast of Maine." (*Id.* at 21:15-17.) "Harvesters, packers, and shippers must

[4] Defendants' expert, Dr. Price, contradicts this assertion somewhat, however, stating that because "HAV is the most heat resistant virus transmitted to humans via food, . . . [t]horough cooking, during the mussel steaming process, may or may not inactivate HAV." (Price Report 2.)

maintain certification and place their certification numbers on special shellfish tags that must accompany all shellfish from the time they are harvested to the time they are portioned or removed from the bag or box." (Costa Report I at 3.) When GEMF buys mussel stock, the harvester's certification tag is already on it. GEMF then "wet stores" the mussels and purges them at its facility in Tenants Harbor, Maine. (Davison Dep. 22:16-23:4.) Before the mussels leave GEMF's plant to be sold to a customer, such as Legal, GEMF affixes its own certification tag.[5] (*Id.* at 23:6-8.)

To arrive at his conclusion that GEMF's mussels were contaminated with HAV, Costa first surmises that GEMF used water from Tenants Harbor, where the plant is located, to purge its mussels. (Costa Report III at 4.) Specifically, he states that "[a]ll of the information [he has] reviewed points to the use of Tenants Harbor seawater as the source of [GEMF] purge water." (*Id.* at 3, 6.) According to Costa, during the relevant period, Tenants Harbor was closed to shellfishing due to pollution under a 1994 order of the Department of Marine Resources ("DMR") that was still effective at the time of his report.[6] Costa believes the Tenants Harbor water was most likely contaminated by "overboard dumping of sewage and the ensuing pollution."[7] (Costa Report III at 2.) It is a "well-established fact," explains Costa, that Maine's

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[5] "[W]et storage means temporary storage, by a dealer, of shellstock . . . in containers or floats in natural bodies of water or in tanks containing natural or synthetic seawater." (Costa Report III at 3.) Wet storage includes purging, which is de-sanding the mussels "in sea water in a 'flow through' system." (*Id.* at 6.)

[6] This DMR Notice of Emergency Rule Repeal and Promulgation is attached to Costa's April 2006 report and states that, effective 1997, of the area from Tenants Harbor to Mosquito Head St. George, which was closed beginning in 1994, only a small cove will be reopened and the rest will remained closed due to pollution. (Costa Report III.)

[7] Costa's report referenced an October 2005 *Washington Post* report tracing an HAV outbreak to oysters contaminated as the result of "overboard dumping of sewage by boaters." (Costa Report III at 1.)

inshore waters are polluted, that Maine "is particularly concerned about the problem of boaters" dumping sewage overboard, and that "Tenants Harbor . . . ranked in the top 10% of inshore waters [in Maine] having a critical need for facilities to provide boaters with sewage disposal methods." (*Id.* at 2-3.) In turn, Costa concludes that GEMF "uses water for wet storage from an area closed to shellfish harvesting."[8]

In further support of his conclusion that GEMF uses or has used contaminated water for wet storing and purging its mussels, Costa cites a "recent Internet article" in which a GEMF partner "describes a new barge as capable of purging shellstock on board, 'if a closure due to red tide is affecting the Great Eastern Plant in Tenant's Harbor.'" (*Id.* at 4.) He also references GEMF's past DMR citations for flaws in its wet storage plan, failure to include detailed wet storage protocol in its HACCP plan, and "not maintaining the pump-out log of the septic tank." (*Id.* at 3-4.) Neither in early 1999 nor today does GEMF use any filters on the water it used to purge its mussels. (Davison Dep. 39:6-18.) Costa criticizes GEMF's assertion that, as primarily a seafood dealer, it need not receive advisories regarding which areas are closed to shellfishing, stating that it prevents GEMF from ensuring that it does not wet store or purge with water drawn from closed areas, including Tenants Harbor. (Costa Report III at 4-5.)

Using water from areas closed due to pollution, according to Costa, undermines a "step in production that is considered crucial to the safety of the mussels in [GEMF's] HACCP plan."

As Costa explains, "[h]uman waste, fecal matter, is the only known reservoir for HAV. . . . Because HAV is highly infectious, even small amounts of human waste in the vicinity of shellfish growing areas may result in contamination of a shellfish harvesting area for quite some time. . ." (*Id.* at 2.)

[8] Costa notes that GEMF does not "include a disinfection step for the water used to purge its shellfish," meaning "either the HACCP plan is deficient in not including this step as critical for the safety of the shellfish, or [GEMF] is not in compliance with the model code, or both." (Costa Report III at 6-7.)

(*Id.* 3-4.) Because of the dangers of harvesting and purging seafood in polluted waters, the State of Maine Department of Environmental Protection ("DEP") "allows, but closely controls, overboard discharges, and prohibits mussel harvesting or use of water from closed areas for any wet storage of mussels." (*Id.* at 2.) GEMF's HACCP plan and the National Shellfish Sanitation Program ("NSSP") 1999 Model Code also require that shellfish only be wet stored with water from approved areas. (*Id.* at 6.)

GEMF, on the other hand, denies ever using purge or wet storage water from areas closed to shellfishing, claiming that it draws its purge and storage water from the ocean and that during the relevant time in 1999, Tenants Harbor, around its purge facility, was open, not closed, to shell fishing.[9] (Davison Dep. 23:15-24:3, 24:5-9.) Costa counters that even if the water was not drawn from a closed area, "shellfish can be contaminated with enteric virus even from approved waters."[10] (Costa Report II at 2.) Defendants' expert, Dr. Price, disagrees, however, stating that he has "not found one case of HAV in the U.S. from approved waters. Actually, [he has] not found one case of HAV from mussels harvested from approved or unapproved growing waters." (Price Report 2.)

In addition to challenging the quality of the purge water, Costa also suggests that the mussels GEMF purchased from independent fisherman may have been harvested in closed waters. GEMF counters that all of the mussels sold to Legal in 1999 came from beds that were,

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[9] GEMF's corporate designee, Davison, states that he "has no idea" whether Tenants Harbor as a whole, was open or closed in 1999. (Davison Dep. 24:10-12.)

[10] One of the epidemiological studies plaintiffs cite, the 2004 report by Fiore, on the one hand bolsters Costa's point, stating that "[i]dentification of HAV in shellfish taken from approved areas in the United States has . . . been reported," but on the other hand states that there have been no cases of HAV caused by shellfish "reported recently" in the United States. (Pls.' Ex. 9, Anthony E. Fiore, Hepatitis A Transmitted by Food 709 [hereinafter Fiore Report].)

according to the harvesters' tags, open to shell fishing. (Davison Aff. 24:17-21.) Costa responds that GEMF's system of monitoring the mussels it purchases is inadequate, pointing to a 2001 DMR citation of GEMF for "relying simply on the presence of a tag, without a written procedure in the HACCP plan for checking the tag to see that the tag information included the name of the person harvesting the mussels and a licensed harvest location."[11] (Costa Report III at 3.) Costa additionally explains that the tag procedure "does not guarantee the safety of shellfish or even that the shellfish came from approved sources, as it is well known that many problems exist with certification tags and other problems in the industry." (*Id.* at 3.) Furthermore, GEMF admits it does not conduct microbiological testing, a required corrective action in its HACCP plan, because "[a]ll of the testing is done by the state of Maine." (Davison Dep. 38:16-18, 39:20-40:21.)

E.

The record contains scant epidemiological evidence regarding the prevalence of HAV in mussels, or even shellfish generally, to support Costa's claims that "[t]he public health literature, the Centers for Disease Control and Prevention ("CDC") and the medical literature recognize that shellfish is a significant vehicle for foodborne viral infection including hepatitis A infection" (Costa's Report III at 1), that "[s]hellfish, especially raw or uncooked shellfish, have some of the highest risk of being contaminated with HAV" (Costa Report I at 2), and that "there is a well-established link between shellfish and Hepatitis A" (Costa Report Nov. 2004 at 1). The epidemiological evidence plaintiffs and Costa offer regarding the prevalence and characteristics

[11] According to Costa's report, this flaw in GEMF's process has since been corrected as part of its HACCP plan. (Costa Report III at 3.)

of HAV in food consists of (1) CDC outbreak data from the years 1993-1997 (Pls.' Ex. 14 [hereinafter CDC data]), (2) a 1984 report by Gary Richards entitled *Shellfish-Associated Enteric Virus Illness in the United States, 1934-1984* (Pl.'s Ex. 8 [hereinafter Richards Article]), and (3) a 2004 report by Anthony Fiore entitled *Hepatitis A Transmitted by Food* (Pls.' Ex. 9, Fiore Report). Costa also provides the results of his own research, which "has revealed that from 1990 to 2002 there were at least 93 outbreaks of Hepatitis A that could be associated with food." (Costa Report II at 1.)

The materials plaintiffs cite are largely outdated and do not persuasively establish mussels as a frequent source of HAV. Richards' report counts "1,395 cases of oyster- and clam-associated hepatitis A" from the period from 1961 to 1984, but includes no more recent statistics and makes no mention of mussels. (Richards Article 1.) Fiore's 2004 report states that "[f]oodborne or waterborne hepatitis A outbreaks are relatively uncommon in the United States," contributing to 2%-3% of reported cases per year, but does allow that food could be the source in a considerably larger number of HAV cases because around 50% of reported cases do not have an identified source. (Fiore Report 705-06.) Other characteristics of HAV documented in Fiore's report include that the virus is more prevalent in the western and southwestern United States than in other regions, that HAV "incidence has decreased to historic lows in the United States" since 1999, and "[t]hat the source of most reported foodborne hepatitis A outbreaks has been HAV-infected food handlers present at the point of sale."[12] (*Id.* at 706-07.) With regard to seafood specifically, Fiore states that "[a]lthough reports of shellfish-related hepatitis A

[12] Costa's report also makes clear that sources other than food are often the cause of a patient's HAV. As he states, "many cases are community acquired" and "[i]nfected food handlers who are infectious on the job and handle ready to eat foods are often identified as the source of HAV in foodborne outbreaks." (Costa Report I at 2.)

outbreaks continue to occur in some other countries, none have been reported recently in the United States." (*Id.* at 709.) Costa also cites the CDC food-borne surveillance system, which "reported nine outbreaks involving 125 cases of seafood-related HAV" between 1978 and 1987, two of which, involving 92 cases, were caused by contamination from food handlers. (Costa Report I at 3.)

Legal's expert, Dr. Price, points to epidemiological evidence supporting a conclusion contrary to Costa's regarding the incidence of HAV in mussels. According to Dr. Price, "[f]oods are not a common cause of HAV infection" and "[s]hellfish, especially mussels, are rarely a cause of HAV worldwide, and extremely rarely a cause in the United States." (Price Report 1.) Dr. Price examines more current CDC data, from 1990-2001, and explains that food was the source of the contamination in just one percent of the 286,881 acute cases of HAV reported to the CDC.[13] (*Id.*) Of that one percent, "[t]here were no reported cases of HAV from shellfish or mussels"; the foods most commonly contaminated with HAV were frozen strawberries, lettuce, sandwiches, bakery goods, and green onions. (*Id.*) Dr. Price also describes the six most recent HAV outbreaks associated with shellfish in the United States, which occurred in 1973, 1988, 1992, 1994, 1998, and 2000, which involved oysters and clams, but not mussels. (*Id.* at 1-2.) In addition, "[t]he latest safety information from the Food and Agriculture Organization of the United Nations (2004) mentions the HAV outbreak in Shanghai, China, in 1988 where more than 290,000 people were infected by eating clams harvested in a sewage polluted area," but makes no mention of HAV from mussels. (*Id.* at 2.)

[13] Costa challenges the veracity of this assertion, stating that Dr. Price "does not site [sic] the CDC publication he is referring to, and therefore it is difficult to form an opinion about this statement." (Costa Report Nov. 2004 at 2.) It is worth noting, however, that the CDC data Dr. Price cites here seems supported by the Fiore report plaintiffs' cite. (*See generally* Fiore Report.)

Costa's explanations of the lack of epidemiological evidence linking mussels, shellfish, and food generally to cases of HAV are that "[f]oodborne illness is vastly under reported, and identifying HAV outbreaks is difficult due to the long incubation period." (Costa Report II at 2.) As Costa says, "for 48% of the people who get Hepatitis A, a cause cannot be positively identified, yet CDC states that many of these cases are actually foodborne." (*Id.*) In addition, "[t]he [three month] delay in presentation of hepatitis A symptoms confounds surveillance for outbreaks of hepatitis A." (Costa Report III at 2.)

II.

Defendants move, pursuant to Federal Rule of Civil Procedure 702 ("Rule 702"), to exclude Dr. Galati's and Costa's testimony that Legal's mussels caused the Fosters' HAV. Defendants argue the testimony should be excluded because (1) Dr. Galati and Costa are not sufficiently qualified as experts to offer an opinion that Legal's mussels were the source of the Fosters' HAV exposure, and (2) even if they were so qualified, their methodologies are not sufficiently reliable under Rule 702.[14] (Legal's Mem. Supp. Summ. J. 8.) For the reasons that follow, the causation testimony of both experts will be excluded.

Rule 702 governs the admissibility of expert testimony.[15] *Daubert v. Merrell Dow*

[14] As a third reason for exclusion, defendants argue that "the experts themselves have by their own testimony shown why their opinions have no basis and indeed are more than likely wrong." (Legal's Mem. Supp. Summ. J. at 8.) This argument is essentially a subset of defendants' argument that the experts' reasoning and methodology is not sufficiently reliable as required by Rule 702 and will be addressed as such.

[15] Federal Rule of Evidence 702 provides:

> If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise, if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has

Pharm., Inc., 509 U.S. 579, 587-88 (1993). The party seeking to introduce an expert's opinions bears the burden of establishing that the "pertinent admissibility requirements are met by a preponderance of the evidence." Fed. R. Evid. 702 advisory committee notes (citing *Bourjaily v. United States*, 483 U.S. 171 (1987)). A trial judge, acting as gatekeeper, is guided by two overarching, but competing, principles when deciding whether to admit an expert's conclusions. First, Rule 702 was intended to liberalize the introduction of relevant expert testimony and thus encourages courts to rely on vigorous cross-examination and presentation of contrary evidence to counterbalance expert opinions of uncertain veracity.[16] *See Daubert*, 509 U.S. at 588, 596; *Westberry v. Gislaved Gummi AB*, 178 F.3d 257, 261 (4th Cir. 1999). Simultaneously, however, a trial court must mind the high potential for expert opinions to mislead, rather than enlighten, a jury. *Westberry*, 178 F.3d at 261.

While the Fosters state that they intend to offer their experts' testimonies to educate the jury on a number of issues,[17] defendants specifically challenge the experts' causation conclusions. The opinions defendants move to exclude are (1) Dr. Galati's conclusions that Ryan's HAV was more likely than not caused by Legal's mussels and that Juliet likely

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applied the principles and methods reliably to the facts of the case.

[16] Indeed, "[a] review of caselaw after *Daubert* shows that the rejection of expert testimony is the exception rather than the rule." Fed. R. Evid. 702 Adv. Comm. notes.

[17] Plaintiffs argue Costa's and Dr. Galati's testimonies will help enlighten the jury on "the appropriateness of the food handling practices of GEMF; the appropriateness of the food handling practices of Legal; the appropriateness of the HACCP plans utilized by GEMF and Legal at the time of the complaint; and whether the undercooked mussels were the source of the hepatitis A that sickened the Fosters." (Pls.' Opp'n 18.) The first three of the above purposes are irrelevant, however, if causation is not established.

contracted HAV from either Legal's mussels or Ryan, and (2) Costa's conclusions that the HAV was caused by GEMF's use of polluted Tenants Harbor seawater to purge its mussels and that improper preparation of the mussels Legal served the Fosters allowed the HAV to survive. Defendants' arguments that the experts' qualifications and underlying methodologies are insufficient and unreliable are discussed in turn below.

A.

Under Rule 702, to be "qualified" as an expert, a witness must have "knowledge, skill, experience, training, or education" in the subject area in which he intends to testify. Fed. R. Evid. 702. An expert's qualification depends on "the nature of the opinion he offers." *See Gladhill v. Gen. Motors Corp.*, 743 F.2d 1049, 1052 (4th Cir. 1984). I will assume without deciding that Dr. Galati and Costa are qualified to testify that Legal's mussels caused the Fosters' HAV.

B.

Even where an expert is qualified to provide an opinion on a particular subject, however, his testimony is not admissible if its underlying methodology does not satisfy Rule 702. *See e.g.*, *Kumho Tire Co. v. Carmichael*, 526 U.S. 137, 153 (1999) (upholding the trial court's finding that the expert's qualifications were sufficient, but his methodology was unreliable). Courts interpret Rule 702 as requiring trial judges to act as gatekeepers, only admitting expert testimony where the underlying methodology satisfies a two-prong test for (1) reliability and (2) relevance. *See Daubert*, 509 U.S. at 589; *Adams v. NVR Homes, Inc.*, 141 F. Supp. 2d 554, 565 (D. Md. 2001). In the instant case, defendants challenge the first prong – the reliability – of the proffered expert testimony, specifically the conclusions that GEMF's and Legal's mussels were more

likely than not the source of Ryan's, and possibly Juliet's, HAV.[18]

To satisfy Rule 702's "reliability" prong, expert testimony "must be supported by appropriate validation." *Daubert*, 509 U.S. at 590 (1993); *Kumho Tire Co.*, 526 U.S. at 149 (1999); *Aldridge v. Goodyear Tire & Rubber Co.*, 34 F. Supp. 2d 1010, 1023 (D. Md. 1999) (interpreting Rule 702 to "require[] some objective, independent validation of the expert's methodology") (internal citations omitted). A court will not "credit an expert witness who 'testifie[s] to no customs of the trade, refer[s] to no literature in the field, and [does] not identify [relevant principles],' but merely [gives] 'his own subjective opinion.'" *Freeman v. Case Corp.*, 118 F.3d 1011, 1016 (4th Cir. 1997) (quoting *Alevromagiros v. Hechinger*, 993 F.2d 417, 421 (4th Cir. 1993)). Although the four *Daubert* factors guide a court's reliability determination, it is a flexible inquiry tailored to the specific facts and opinions before the court.[19] *See Kumho Tire Co.*, 526 U.S. at 150 ("[T]he law grants a district court the same broad latitude when it decides *how* to determine reliability as it enjoys in respect to its ultimate reliability determination.") (emphasis in original).

Broadly speaking, defendants launch the same challenges to each expert's methodology. First, defendants argue that Dr. Galati's and Costa's causation conclusions are devoid of underlying methodology; "[r]ather, the opinions at issue have been based upon assumptions without reference to a scientific technique, study, or theory." (Legal's Mem. Supp. Summ. J. 12-

[18] Because causation is an essential element of each of plaintiffs' claims, the experts' causation testimony clearly satisfies the second prong for relevance.

[19] The four *Daubert* factors are: (1) whether the expert's theory or technique has been tested; (2) whether the theory or technique has been subjected to peer review and publication; (3) the methodology's known or potential rate of error; (4) the method's or conclusion's acceptance within the relevant community. *Daubert*, 509 U.S. at 593-94.

13.) Instead of relying upon a "novel scientific methodology, analysis, or test," defendants claim, the experts base their conclusions on assumptions and unsupported propositions. (*Id.* at 13.) Additionally, and more persuasively, defendants argue that to the extent the experts did employ some underlying methodologies, they are not reliable because they fail to rule out, or at least minimize, alternative causes as required for a valid causation opinion. (*Id.* at 14-16.) *See Kumho Tire*, 526 U.S. at 153 (explaining that even where experts employ a recognized methodology, they may not apply it correctly in a given context). Specifically, defendants argue that the methodologies are unreliable because they ignore data regarding other potential causes of the Fosters' HAV, such as "eating food outside the home or contact with people in southern Texas." (Legal's Mem. Supp. Summ. J. 15-16.)

For the reasons that follow, the causation testimonies of Dr. Galati and Costa will be excluded on the grounds that their underlying methodologies are not sufficiently reliable.

i.

Defendants move to exclude Dr. Galati's causation testimony as based on an inadequate methodology that led to an unreliable differential diagnosis. First, defendants argue that Dr. Galati "supports his opinion with 'simply the well-known fact that shellfish are associated with HAV infection and that undercooked shellfish or raw shellfish would allow the virus to survive.'" (*Id.* at 13.) In addition, defendants posit that Dr. Galati's differential diagnosis is unreliable because he fails to account for alternative causes of the Fosters' HAV.

Where, as is the case with Dr. Galati, a medical expert opines as to the source of a plaintiff's condition, he frequently employs a "differential diagnosis" to establish the most likely cause. A differential diagnosis, which courts have recognized as a reliable methodology when

conducted properly, "is a standard scientific technique of identifying the cause of a medical problem by eliminating the likely causes until the most probable one is isolated." *Westberry*, 178 F.3d at 262. This process "typically, though not invariably, is performed after 'physical examination, the taking of medical histories, and the review of clinical tests, including laboratory tests.'" *Roche v. Lincoln Prop. Co.*, 278 F. Supp. 2d 744, 751 (E.D. Va. 2003) (quoting *Westberry*, 178 F.3d at 262). To be reliable, a differential diagnosis must first "rule in" a plaintiff's proposed cause and then "rule out" alternative causes. *See Westberry*, 178 F.3d at 263. "Ruling in" a cause, also known as proving "general causation", "is established by demonstrating that exposure to a substance can cause a particular disease." *Doe v. Ortho-Clinical Diagnostics, Inc.*, 440 F. Supp.2d 465, 471 (M.D.N.C. 2006) (internal citations omitted). To complete a differential diagnosis, an expert must then "rule out" alternative causes, which means opining as to "specific or individual causation" by "demonstrating that a given exposure is the cause of a particular individual's disease." *Id.* (internal citations omitted). As a general rule, "it is not appropriate to rely on a differential diagnosis to prove general causation," but establishing general causation is an essential prerequisite to proving specific causation. *Id.* at 471, 477.

As an initial matter, I reject defendants' argument that Dr. Galati reached his causation conclusions without relying on an underlying methodology. Dr. Galati described his approach to uncovering the cause of Ryan's HAV as follows:

> We . . . took a history and asked for usual routes of exposure and contamination. And what we were told was that [the Fosters] had this episode at a restaurant where they felt that they had some undercooked seafood. And . . . we listened to them, and they appeared somewhat adamant that . . . there was some question about whether it was cooked . . . and that it wasn't quite cooked well enough. But we asked other questions about potential exposures, and my recollection is that

there was . . . nothing else that really came to light.

(Galati Dep. 25:7-18.)

Dr. Galati went on to describe his first consultation with Ryan where they "talked about other viral hepatitis risk factors, we asked about intravenous drug use, homosexual activity, blood transfusions, medications, work history, other contacts, food, water." (*Id.* at 98:17-21.) According to Dr. Galati, taking a detailed history is the customary methodology for investigating the source of a patient's acute HAV: "you take a history . . . and you have to look and see what the most likely risk factor may be. And many times they report that they've had a[n] . . . exposure to seafood, raw foods, et cetera. And then, . . . certainly you'd work back and try to identify the source." (*Id.* at 34:6-11.)

To reliably establish specific causation, Dr. Galati's differential diagnosis must have eliminated, or at least minimized, other potential causes of the Fosters' HAV.[20] This is a close question. After hearing about the undercooked mussels at Legal, "[Dr. Galati] asked other questions about other potential exposures, and [his] recollection is that there was . . . nothing else that really came to light." (*Id.* at 25:15-18.) Dr. Galati explains that, because HAV exposure at an eatery is "statistically quite small," asking about all of the places where Ryan ate was not strictly necessary in forming his opinion – it "could certainly be a question that could be asked or omitted. . . . We probably posed it . . . and [Legal] was the only thing they brought to our attention." (*Id.* at 106:16; 104:1-7.) As Dr. Galati stated, "I am a physician. I talk to my patients. I'm not a lawyer. I'm not a detective other than a medical detective of sorts to try to

[20] The temporal relationship between the onset of symptoms and the Fosters' trip to Legal supports Dr. Galati's conclusion, but because the HAV incubation period is so long, any number of other causes may have intervened.

get the facts." (*Id.* at 114:1-4.) Perhaps understandably, Dr. Galati did not inquire into the food Ryan may have eaten at Burger King and the Bean Bag Café.

Even if Dr. Galati adequately ruled out alternative sources of the Fosters' HAV as part of a reliable differential diagnosis, the available evidence was not sufficiently probative for Dr. Galati to have ruled *in*, from the universe of possible causes, GEMF's and Legal's mussels; in other words, he failed to establish general causation. To rule in Legal's mussels, Dr. Galati relied on Ryan's and Juliet's description of them. Specifically, being served raw mussels at Legal was the only encounter where "there was some bell in [the Fosters'] head that went off." (*Id.* at 111:6-11.) Not only does that strategy overlook and fail to rule in other tasteless, odorless, invisible sources of HAV, like contact with infected persons, which the record makes clear are the most common type, but it also is not supported by the evidence before the court regarding the prevalence of HAV in uncooked mussels. Based on the available epidemiological evidence, the instances of HAV in shellfish, particularly mussels, in recent years is extremely low or nonexistent; other food sources are rare, but more likely than mussels. The fact alone that the mussels were raw does not suggest HAV contamination, but merely that *if* they were contaminated, thorough steaming did not intervene to kill the virus. Accordingly, without questioning Dr. Galati's medical credentials, I find he lacked a sufficient basis for ruling in Legal's mussels as a source of the Fosters' HAV. His causation testimony must therefore be excluded.

ii.

As discussed earlier, plaintiffs' second expert, Roy Costa, draws conclusions with respect to both Legal's and GEMF's roles in the mussel's alleged contamination. According to Costa,

"[t]he most likely source of hepatitis in the mussels consumed by [the Fosters] within a great degree of scientific certainty, certainly greater than 51% is the use of polluted Tenants Harbor seawater by [GEMF] to purge its mussels." (Costa Report III at 8.) Furthermore, it is Costa's opinion that Legal undercooked the mussels, which allowed the HAV to survive. Defendants' first challenge to Costa's methodology, that it "referenced no particular scientific, medical, or other technical proof" (Legal's Mem. Supp. Summ. J. 16), is contradicted by the record. In forming his opinion, Costa reviewed the Fosters' medical records, researched HAV and its causes, including seafood, considered Legal's and GEMF's practices and standards, and compared the onset of the Fosters' symptoms with HAV's incubation period. Nonetheless, I do find Costa's conclusions with respect to causation should be excluded because they are not adequately supported by his methodology.

First, Costa's investigation was seemingly distinct from and less thorough than the epidemiological investigations of illness outbreaks he has conducted over the course of his career. For example, Costa explained that investigating an allegation of HAV at a Taco Bell "required [him] to actually collect the data for the investigation, the date of onset of the employee, symptoms, environmental factors that could have affected the outbreak." (Costa Dep. 30:17-20.) In probing the source of the Fosters' illness, in contrast, Costa did not actually inspect or investigate Legal and its employees regarding the existence of HAV in Legal's mussels, nor did he visit and investigate the GEMF facility. As a result, Costa is not necessarily adhering to the methodology commonly accepted in his practice and field and upon which his experience is based.

In addition, Costa's methodology fails to establish either general or specific causation.

With respect to general causation, Costa fails to reliably rule in mussels as a cause of the Fosters' HAV. The epidemiological studies upon which Costa relies do not provide strong evidence that mussels are a source of HAV; indeed, the cited Fiore report documents food or water as the cause in only 2%-3% of annually reported cases of HAV in the United States, none of which has involved shellfish in recent years. (Fiore Report 705-06, 709.) In addition, Costa cites CDC reports from 1993-1997, ignoring those from more recent years, which, according to Dr. Price, show that HAV cases from shellfish and mussels have declined to near zero. (Price Report 1.)

Furthermore, Costa's general causation conclusion is strained by the fact that the actual batch of mussels the Fosters consumed is no longer available and cannot be definitively ruled in.[21] This absence of tangible proof of contamination distinguishes his methodology here from that in previous investigations, undermining the reliability of his general causation conclusion. Costa's "tracebacks" as a sanitarian were initiated in response to outbreaks where a collection of people who had all eaten at the same establishment became ill, meaning that the establishment was a known source of the contamination. In turn, he was "looking for . . . the source of the infection and the vehicle by which it [was] transmitted. . . . [I]f the source is food, then [he had] to determine whether the food was contaminated intrinsically, meaning because it's a bivalve

[21] Although the resolution of an analogous obstacle confronting the experts in *Westberry* suggests that the impossibility of ruling in these exact mussels should be excused, I find this circumstance distinguishable. In *Westberry*, the experts ruled in talc as a cause of the plaintiff's sinus infection by opining that any talc – in large enough quantities – could cause such an infection. Despite the near impossibility of ascertaining the precise quantity of an individual's workplace exposure to talc, the court admitted the conclusions, stating that while that information would be "beneficial," it "is not always available, or necessary" to ruling in the substance and opining that it caused the plaintiff's illness. *Westberry*, 178 F.3d at 264. Unlike talc, however, harm by exposure to mussels is not cumulative: if the mussels were not contaminated, they would not cause HAV regardless of the quantity consumed. Therefore, the lack of actual evidence of the condition of this batch of mussels is not excusable on the same grounds as the lack of evidence regarding the quantity of talc exposure.

mollusk ingesting or the food is contaminated by a person." (Costa Dep. 33:8-12.) In this case, Costa's starting point is the Fosters' illness, not an outbreak at Legal, rendering his traceback far more disjointed and speculative.

As a result, to establish the existence of HAV in the relevant mussels, Costa relies on his suspicions that GEMF wet stores and purges its mussels in water contaminated by overboard sewage dumping and that Legal received those contaminated mussels but failed to adequately cook them before passing them along to the Fosters. Costa lacks sufficient evidentiary support for those suspicions, however, particularly because he cannot confirm that the mussels were drawn from water closed due to pollution. Instead, he draws hypothetical conclusions from the flaws he pinpoints in GEMF's and Legal's procedures and policies. Without tangible evidence that the deficiencies he presumes are actually occurring or proof that they led to the contamination of *any* mussels, much less the batch in question, Costa's general causation conclusions are simply too speculative to be reliable. As GEMF argues, "what is blatantly missing from the Costa report is any evidence of any findings of any Hepatitis A Virus, at any time, and by any authority, in any area of [GEMF's] facility." (GEMF's Mem. Supp. Summ. J. 14.)

With respect to specific causation, as defendants argue, Costa fails to conduct a reliable investigation because he neither considers nor rules out alternative causes of the Fosters' HAV, such as other contaminated foods they consumed during the incubation period or contact with other infected persons. This failure is especially egregious in light of the Fiore study's evidence that HAV-infected food handlers are the most common source of the virus and that HAV is most common in the western and southwestern United States, where the Fosters live. (Pls.' Ex. 9.)

Costa explained the basis for his conclusion that Ryan contracted HAV from Legal's mussels as follows: Ryan "ate undercooked mussels. Mussels have a history of causing hepatitis. He had an illness within the incubation period." (Costa's Dep. 125:4-14.) With respect to Juliet, Costa explained that "[s]he consumed the same shellfish that her husband did and they both contracted hepatitis."[22] (*Id.* at 126:3-4.)

In determining specific causation, Costa relies almost entirely on the temporal relationship – based on HAV's incubation period – between when the Fosters ate the uncooked mussels and when they contracted the disease. In addition to the fact that a temporal relationship alone cannot sustain a causation opinion, *see Roche*, 278 F. Supp. 2d at 764, HAV's long incubation period diminishes the probative value of a temporal relationship.[23] Furthermore, Costa did not even attempt to identify other possible causes of the Fosters' illness, admitting, "I don't have [Ryan's] food information or [the Fosters'] food history prior to eating at Legal or subsequent to eating [there]." (Costa Dep. 119:4-6.) By not even identifying other sources, Costa had no opportunity to minimize them. Accordingly, expert testimony by Costa that Legal's mussels were more likely than not the cause of the Fosters' illness must be excluded as unreliable and potentially misleading to the jury.

III.

A defendant's motion for summary judgment should be granted "if the pleadings,

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[22] Costa went on to say, however, that "it's very possible that [Juliet] could have contracted [HAV] from [Ryan]. . . But she still falls in very close to what the expected incubation outside parameter might be." (Costa Dep. 126:11-17.)

[23] This is in contrast to illnesses like food poisoning where the close proximity between ingestion of the contaminated food and the onset of symptoms can more convincingly bolster a causation opinion. *See, e.g., Starr v. Oriole Cafeterias, Inc.*, 182 Md. 214, 216, 34 A.2d 335 (1943); *Armour & Co. v. Leasure*, 177 Md. 393, 400, 9 A.2d 572 (1939).

depositions, answers to interrogatories, and admissions on file show that there is no genuine issue as to any material fact and the moving party is entitled to a judgement as a matter of law." Fed. R. Civ. P. 56(c); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986). A dispute about a material fact is genuine, and summary judgment is inappropriate, if the evidence is such that a reasonable jury could return a verdict for the nonmoving party. *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 248 (1986). In analyzing whether a genuine issue of material fact exists, the evidence and reasonable inferences from that evidence must be viewed in the light most favorable to the nonmoving party. *Id*. at 255. Nonetheless, if "after adequate time for discovery and upon a motion," the nonmoving party "fails to make a sufficient showing to establish the existence of an element essential to that party's case," a court must enter summary judgment in favor of the moving party. *Celotex Corp.*, 477 U.S. at 322; *Anderson*, 477 U.S. at 249-50 (internal citations omitted) (holding that where "the evidence is merely colorable or is not sufficiently probative, summary judgment may be granted").

Without Dr. Galati's and Costa's causation testimony plaintiffs have insufficient probative evidence that mussels from GEMF and Legal caused the Fosters' HAV. Even assuming for the purposes of this motion that Legal served the Fosters raw mussels, that fact alone, particularly considering HAV's long incubation period, is insufficient to create a triable issue for the jury since the evidence demonstrates that the vast majority of raw mussels are not contaminated. Similarly, accepting that GEMF does have a practice of purging its mussels with closed water, without any evidence that practice has led to contamination and considering the low incidence of contaminated mussels from *any* water, there is no triable issue. In addition, scant epidemiological evidence that mussels occasionally, but rarely, carry HAV, when person-

to-person contact and other foods are far more likely sources of the virus, is not sufficiently probative to create a triable inference that the uncooked mussels in question infected the Fosters. Finally, the timing of the Fosters' illnesses, with Juliet contracting HAV three weeks later than Ryan, provides circumstantial evidence that the shared mussels were not the source but rather that Ryan contracted HAV from an alternative source and subsequently passed it on to Juliet, as does the absence of other reported cases of HAV in Baltimore or associated with Legal or GEMF.

Because plaintiffs fail to present sufficient evidence to present a genuine issue of material fact with respect to causation, summary judgment for defendants will be granted by separate order.

July 25, 2008
Date

/s/
Catherine C. Blake
United States District Judge